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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,882	03/02/2000	DUNCAN MCGREGOR	1015-00	3081

34661 7590 03/22/2007
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EXAMINER

GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/486,882	MCGREGOR, DUNCAN	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7,9 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/20/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Responsive to communications entered 11/20/2006. Claims 1,3-7,9,24-26 are pending.

Claims 1,3-7,9,24-26 are under consideration.

Priority

This application is a 371 of PCT/GB98/02630, which claims priority to UK application 9718455.0, filed 9/2/1997.

Receipt is once again acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Withdrawn Rejections

The rejection of claims 1,4-7,9,24-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1,3-7,9,24-26 under 35 U.S.C. 103(a) as being unpatentable over **Rebar et al** (1994 Science 263:671-673) in view of **Lannigan et al** (1989 PNAS 86:863-867) has been withdrawn in view of applicant's persuasive arguments.

Maintained Claim Rejections - 35 USC § 112 First Paragraph

Claims 1,3-7,9,24-26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Response to Arguments

Applicants argue, see p 6-7 (11/20/2006) that they were in possession of the claimed invention because the skilled artisan can immediately envision other species in the genus of nuclear steroid receptors capable of binding single stranded DNA.

Specifically, applicants quote abstracts from Hughes et al (1981 Biochemistry 20:2481-2491), Franceschi (1984 PNAS 81:2337-2341) and Lin et al (1981 Biochim Biophys Acta 654:181-186) as evidence that those of ordinary skill in the art were well aware that nuclear steroid receptors were capable of binding single stranded DNA prior to the filing date of the instant application.

It is noted, however that the instant claims are drawn to a "nucleotide sequence motif which is specifically bound" Hughes teaches "No DNA-sequence specificity was identified for the binding of the [progesterone] receptor protein" Franceschi teaches testing *total* intestinal RNA against the 1-alpha,25-dihydroxyvitamin D3 receptor, which represents a non-specific assay. Lin et al teach "the receptor appears to bind mRNA, tRNA and rRNA," indicating the androgen receptor binds to three structurally distinct species of RNA (i.e. non-specifically). In conclusion, the teachings of Hughes, et al, Franceschi and Lin et al are not commensurate with the specificity limitation of the claimed subject matter. Furthermore, one of ordinary skill in the art at the time the invention was made would not be able to predict the requisite specific nucleic acid

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binding sequence and would not be placed in possession of the claimed invention based on the instant disclosure (see also enablement considerations below).

Claiming a product based on an assay was considered in *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) where the court affirmed that the description of the COX-2 enzyme did not serve to describe unknown compounds capable of selectively inhibiting and/or binding to that target.

In particular, the patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that “[w]ithout such disclosure, the claimed methods cannot be said to have been described.

In the instant case, see arguments p 6-7 (11/20/2006), applicant has provided evidence of steroid receptors which bind DNA sequences non specifically, but the disclosure does not provide sufficient written description of nucleotide sequence(s) capable of specifically binding the entire genus of nuclear steroid receptors in accordance with *Rochester* (see above).

Claims 1,3-7,9,24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the species of chimeric fusion proteins comprising the estrogen receptor, it does not reasonably provide enablement for the genus of nuclear steroid receptors capable of binding single stranded DNA. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Response to Arguments

Applicants argue, see p 7-8 (11/20/2006) procedures for determining whether or not a nuclear steroid receptor is capable of binding to single stranded DNA were well established and well known long before the priority date of this application.

Specifically, applicants quote abstracts from Norby et al, Pierrou et al, Alex et al, Thiesen et al and Wright et al as examples concerning methods directed toward finding single stranded DNA binding protein recognition motifs.

It is noted, however that the instant claims are drawn to a single stranded polynucleotide. Norby et al teaches "a pool of double stranded oligonucleotides" Pierrou et al teaches a double-stranded oligonucleotide for which the central 32 bp have been randomized. Thiesen et al teach random double stranded oligonucleotides harboring a PCR primer. While the abstract of Alex et al is silent with regard to the nucleotide composition, pg 2259 line 3 of the original reference indicates that GST-N-MYC protein was incubated with [a] double stranded oligonucleotide mixture. While the abstract of Wright et al is silent with regard to the nucleotide composition, pg 4105, line

2 of the original reference indicates that myogen GST fusion protein was incubated with double stranded DNA.

In conclusion, the teachings of Norby et al, Pierrou et al, Alex et al, Thiesen et al and Wright et al are not commensurate with the single stranded limitation of the claimed subject matter. Furthermore, one of ordinary skill in the art at the time the invention was made would not be able to predict the requisite single stranded nucleic acid binding sequence for an uncharacterized nuclear steroid receptor without undue experimentation based on the instant disclosure.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON EPPERSON
PRIMARY EXAMINER

Christopher M Gross
Examiner
Art Unit 1639

cg

A large, stylized handwritten signature in black ink, likely belonging to Christopher M. Gross, is written over the signature block.